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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,632	11/16/2007	Gert Bolander Jensen	ZBM1.001APC	2289

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EXAMINER	
KIM, YOUNG J	

ART UNIT	PAPER NUMBER
1637	

NOTIFICATION DATE	DELIVERY MODE
09/23/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/590,632	JENSEN ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 August 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/25/07 & 3/20/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

The specification is objected to by the Examiner because it claims benefit of the filing date of the international application of which it is the national stage. A national application filed under 35 U.S.C. 371 may not claim benefit of the filing date of the international application of which it is the national stage since its filing date is the date of filing of that international application. Since the international application is not an earlier application (it has the same filing date as the national stage), a priority claim in the national stage to the international application is inappropriate. Accordingly, it is not necessary for the applicant to amend the first sentence of the specification to reference the international application for a national stage application filed under 35 U.S.C. 371 (See also MPEP 1893.03(b)).

Information Disclosure Statement

The IDS received on January 25, 2007 and March 20, 2007 are proper and are being considered by the examiner.

Reference 37 in the IDS received on January 25, 2007, Boe et al., has not been considered because the PTO does not have a record of this reference.

Reference 59 in the IDS received on January 25, 2007, does not comply with the requirements set forth in the 37 CFR. 1.97 in that the publication year is missing from the citation.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because some of the Figures are not clearly visible. For example, Figure 8 is barely visible. Applicant is advised to employ the services of a competent patent draftsperson outside the Office,

as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

The specification is objected to for the following informalities.

On page 8, line 23 of the instant specification, a PCT application number is referred to, but only disclosed as, "Application No. XXXXXXX."

On page 11, a PCT application number is referred to, but only disclosed as, Application No. ZZZZZZZ."

On page 16, a PCT application number is referred to, but only disclosed as, "Application No. YYYYYYY."

Applicants are advised to peruse the entire specification to identify and correct such defects. In addition, Applicants are reminded that no new matter can be introduced and that sufficient evidence must be presented for allowing entry of any PCT numbers into the specification[1], wherein the teachings of these PCTs are incorporated by reference.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[1] Applicants should provide sufficient evidence that the PCT numbers being amended thereto is the same PCT which the Applicants had contemplating in incorporation by reference.

Claims 5, 6, 13, 14, 16, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "said nucleic acid probe." There is insufficient antecedent basis for this limitation in the claim. It would appear that the proper antecedent basis can be found from the limitation, "oligo-nucleic acid probe."

Claims 6 and 16 are indefinite by way of their dependency on claim 5.

Claim 13 is drawn to, "a chip" but later recites the phrase, "the method comprising."

A claim must be either a product or a method. For the purpose of prosecution, the claim is deemed to be drawn to a product - a chip.

Claim 14 is indefinite for reciting the limitation, "an electrical interface between the device and the chip for applying an alternating electric field between a first and a second electrode of the chip or the device."

If the electrical interface is to be achieved between the device and the chip, the first and the second electrode must be found on the device, and not on the chip. As currently recited, it is not clear that the first and second electrode is found on the device, but rather appears to be solely found on the chip.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the device performs all of the actions recited in the Markush group. The device is for detecting a biological particle from a gaseous sample. The device, however, has a programmable unit that performs "one or more" actions of the recited Markush elements. For example, the device cannot detect a biological particle with a programmable unit that

performs solely the step of providing a gaseous sample in the sample chamber, nor can the programmable unit that performs solely applying a field potential between the two electrodes.

All steps must be conducted by the programmable unit for the detection to occur by using the claimed device.

Claim 17 recites the phrase, "at least the copy of the amplified target nucleic acid." It is unclear which copy "the" copy is referencing to. Correcting the phrase to recite, "at least a copy of the amplified target," would overcome the rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Birmingham et al. (U.S. Patent No. 5,989,824, issued November 23, 1999) in view of Mainelis et al. (Aerosol Science and Technology February 2002, vol. 36, pages 1073-1085; IDS[2] ref# 56).

Birmingham et al. Disclose a method of detecting biological particles from gaseous sample (Air, see Figure 1, elements 14 and 16), said method comprising:

a) providing said gaseous sample into a sample collector and concentrator (thus a sample chamber; Figure 2B, element 50 "fluid flow" – column 6, lines 27-28);

b) contacting the collected biological particle (spores, see column 2, lines 46-47) with a liquid agent (column 2, lines 60-62, in the phrase, "[i]n an alternative preferred embodiment, the ionizing

discharge is employed to ionize a fluid, producing an ionized fluid that ruptures the surface membrane of the cell.");

c) exposing said liquid agent to an electric field in the sample chamber (column 2, line 66 to column 3, line 2, in the phrase, "the cell is conveyed past an ionizing discharge from an electrode that lyses the cell.") having a sufficient amplitude so as to enable extraction of biological material from the biological particle (column 4, lines 54-60, in the phrase, "[t]he spore lysing apparatus, which is configured in accord with the present invention, facilitates cleavage and rupturing of the surface membrane around each of the bacterial cells and/or spores comprising the specimen…it is important to expose the DNA and RNA comprising the nuclear material contained within the surface membrane of these bacterial spores and cells"; column 6, lines 61-65);

d) performing analysis of the extracted biological material (column 5, lines 3-4), wherein the artisans explicitly state that device comprise those which conducts (PCR, column 5, line 29-32), which would result in the measurement of the amplified nucleic acid sequence (column 5, lines 31-33).

Birmingham et al. do not explicitly disclose that a first and second electrode is provided and that the chamber is positioned so that at least part of the sample chamber is between the first and the second electrode, and that a potential is applied to the first and second electrode so as to assist electrostatic collection of the biological sample into the chamber.

Birmingham et al. do not explicitly disclose that the distance between the first and the second electrode is at most 20 mm.

Birmingham et al. do not explicitly disclose that the liquid agent which forms a mixture with the contacted biological particle comprises one or more reagents required to perform a nucleic acid

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amplification, or that the first liquid reagent comprises one or more reagents selected from the group consisting of a primer, a triphosphate nucleotide and a polymerase.

While Birmingham et al. disclose a device which collects, lyses, and conducts DNA/RNA analysis on a single chip, the artisans do not explicitly state that a device comprising a first and a second electrode, a heating electrode, and a temperature sensing element, nor an apparatus configured for such a purpose.

Mainelis et al. disclose a device comprising 2 electrodes, spaced at a distance of 20 mm (page 1074, 2nd column, 2nd paragraph; page 1075, Figure 1A, height, "H"), wherein the artisans employ said device to generate an electrical field, for the purpose of collecting bacterial spores from air samples (thus gaseous; see page 1077, 1st column, 4th paragraph).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Birmingham et al. with the teachings of Mainelis et al., thereby arriving at the claimed invention for the following reasons.

The motivation to arrive at a device which conducts the steps of collecting biological spores from gaseous sample, followed by their lysis with an electrical field, and followed by their analysis, for the advantage of producing portable devices for military usages, has been known in the art, as clearly expressed by Birmingham et al.:

> "One of the more important applications of technology requiring the lysing of bacterial cells and/or spores is in facilitating identification of biological agents that are used during bacteriological warfare or in attacks by terrorists. In order to permit known harmful bacteria to be identified, it is important that DNA and RNA comprising the bacterial cells or spores found in the suspect environment be made available for analysis. By providing a reliable and portable apparatus for lysing bacteria cells or spores collected from the environment, it will be possible to identify bacteriological warfare agents in the field so that appropriate counteractive and protective measures can be implemented. A portable field monitoring device that includes the capability to collect, concentrate, lyse, and identify bacteriological warfare agents will greatly enhance the ability of civilian populations and troops to survive such attacks." (column 2, lines 24-39, Birmingham et al.)

As discussed already above, Birmingham et al. disclose a method and a use of a device that collects the air sample by flow into the device, followed by the lysis of the bacterial spores therein via electric field, followed by the analysis of the extracted DNA/RNA therefrom.

While Birmingham et al. do not employ a first and a second electrode which is spaced apart at the distance of 20 mm, for the initial capture of the bacterial spores, one of ordinary skill in the art at the time the invention was made would have been motivated to combine the teachings of Mainelis et al., wherein the artisans state that with the use of electrostatic capture method, they were able to achieve about 90% collection efficiency (page 1078, 1st column) when collecting bacterial spores from a gaseous sample.

Figure 3 of Mainelis et al. clearly show the efficiency rate collection of bacterial spores from air with the electrostatic enhancement versus no electrostatic enhancement (see collection efficiency with voltage near zero).

Since the invention disclosed by Birmingham et al. was focused on the detection of biological warfare agents in the field, one of ordinary skill in the art would have recognized that collection efficiency of the bacterial spores in the air would have been a critical element, allowing for higher sensitivity in detection of harmful agents in the air.

Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to combine the teachings of Birmingham et al. with the teachings of Mainelis et al., so as to arrive at a device and a method of using said device for the efficient capture of bacterial spores from air, followed by their lysis, and subsequent analysis of the DNA/RNA typing, with a reasonable expectation of success.

With regard to the inference of the amplified nucleic acid being indicative of the presence of the biological particle, Birmingham et al. clearly state that immuno-PCR would be useful in

identifying the DNA/RNA (column 5, lines 29-33). Therefore, one of ordinary skill in the art would have inferred that the presence of such bacteria would have been present in the sample, when conducing said immuno-PCR method for the analysis part of their method.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Claims 3, 4, 7-9, 13-15, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Birmingham et al. (U.S. Patent No. 5,989,824, issued November 23, 1999) in view of Mainelis et al. (Aerosol Science and Technology February 2002, vol. 36, pages 1073-1085; IDS[3] ref# 56), as applied to claims 1, 2, and 17 above, and further in view of Johns et al. (Letters in Applied Microbiology, 1994, vol. 18, pages 236-238; IDS[3] ref# 47).

The teachings of Birmingham et al. and Mainelis et al. have already been discussed above.

While Birmingham et al. disclose that any kinds of DNA/RNA analysis could be conducted, the artisans do not explicitly disclose that a nucleic acid amplification detection should be conducted for measuring the presence of the amplified target nucleic acid, or that nested-PCR be conducted, or that a chip configured for such a purpose, or that a device which is configured for housing such a chip be produced.

Johns et al. disclose a method of detecting *Bacillus anthracic* in spores by use of PCR (Abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Birmingham et al. and Mainelis et al., with the teachings of Johns et al., thereby arriving at the claimed invention for the following reasons.

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Birmingham et al., while not explicit in stating that a PCR be conducted for the DNA/RNA analysis followed by the spore lysis and extraction of DNA/RNA therefrom, the artisans clearly imply any type of DNA/RNA analyses available in the art could be employed:

> "Once the surface membranes of the bacterial cells and/or spores have been ruptured by lysing apparatus...,the exposed nuclear material comprising specimen…is carried by conveyer...to a spore or cell RNA/DNA identifier...This identifier processes the nuclear material to identify the specific type of bacterial cells and/or spores comprising the specimen. The device preferably used for identifying the type of bacteria in the specimen is a time of flight mass spectrometer. However, a number of other types of bacterial spore and cell identifiers might alternatively be used..." (column 5, lines 1-10, Birmingham et al.)

Johns et al. clearly demonstrate to one of ordinary skill in the art that anthrax can be identified from its spores by polymerase chain reaction (Abstract), wherein the artisans extract DNA from spores of anthrax, and conducts PCT (page 236, 2nd column).

The artisans state that the disruption of the spores prior to the PCR amplification provided faster and sensitive result (page 237, 2nd column, Johns et al.):

> "Germination of spores in PBS/150 mmol/l L-alanine/6 mmol/l OCDS prior to PCR increased sensitivity to allow for the detection of 10 spores per test. But although this procedure gave very sensitive PCR result, it was slow. As mechanical disruption might be more rapid, we decided to evaluate the use of … to mechanically disrupt spores...Equivalent sensitivity in PCRs from germinated and mechanically disrupted spores..." (page 237, 2nd column, Johns et al.).

Therefore, one of ordinary skill in the art at the time the invention was made would have clearly recognized that the use of PCR for identifying bacterial spores, wherein said spores have been disrupted, would have yielded their sensitive detection.

One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success at producing the combine invention given the fact that Birmingham et al. identifies the extracted DNA/RNA from the bacterial spores by first lysing said

spores. Since Johns et al. clearly demonstrate that PCR can be conducted from lysed spores of anthrax, one of ordinary skill in the art would have been motivated to combine the teachings of the artisans, thereby arriving at the invention as claimed.

With regard to the limitations drawn to the chip and apparatus, which is configured for conducting PCR (i.e., heating electrode, a temperature sensing element), it is respectfully submitted that the art is replete with miniature devices for conducting PCR, which comprises heating electrode and temperature sensing elements, and the Office is taking official notice for this teaching. Should Applicants challenge this fact, such evidence would be provided in a subsequent Office Action, but nevertheless be made final.

MPEP 2144.03(D) states the following in such a situation:

> "If the examiner adds a reference in the next Office action after applicant's rebuttal, and the newly added reference is added only as directly corresponding evidence to support the prior common knowledge finding, and it does not result in a new issue or constitute a new ground of rejection, the Office action may be made final."

Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to arrive at the device and apparatus for conducting the method of the combined teachings of the artisans, as the motivation to conduct such a method would have been present to said one of ordinary skill in the art, and producing a device/apparatus for such a purpose would have been well within the purview of an ordinarily skilled artisan.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Claims 5, 6, 10-12, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Birmingham et al. (U.S. Patent No. 5,989,824, issued November 23, 1999) in view of Mainelis et al.

(Aerosol Science and Technology February 2002, vol. 36, pages 1073-1085; IDS[4] ref# 56), as applied to claims 1, 2, and 17 above, and further in view of Braven et al. (WO 03/074731 A2, published September 12, 2003, filed February 11, 2003; IDS[4] ref# 34).

The teachings of Birmingham et al. and Mainelis et al. have already been discussed above.

While Birmingham et al. disclose that any kinds of DNA/RNA analysis could be conducted, the artisans do not explicitly disclose that a nucleic acid amplification detection should be conducted for measuring the presence of the amplified target nucleic acid, wherein said amplification is detected by electrochemical means, involving oligonucleotide probes which release redox active component upon their degradation, wherein the measurement of such degradation is measured by voltammetry, or that a chip configured for such a purpose, or that a device which is configured for housing such a chip be produced.

Braven et al. disclose a method and a device for probing for a nucleic acid comprising contacting a nucleic acid solution with an oligonucleotide probe labeled with an **electrochemically active marker**, providing conditions at which the probe is able to hybridize with any complementary (target) sequence which may be present in the nucleic acid solution, **selectively degrading either hybridized or unhybridised nucleic acid probe**, and electrochemically determining information relating to the electrochemically active marker (page 3, line 30 to page 4, line 5)

Braven et al. state that the term, "degrade" includes degradation as a result of enzyme activity, for example by digestion. (page 3, line 30 through page 4, line 5).

In a specific embodiment, Braven et al. disclose that a 5' nuclease activity of *Taq* polymerase or a similar enzyme may be used to digest a nucleic acid probe which has hybridized at a position on

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the target between a pair of PCR primers would be employed for detection, wherein such a case, the probe would be digested concomitant to primer extension." (page 4, lines 13-16)

Braven et al. also explicitly disclose that their present invention is based on the observation that an electrochemically active marker such as matallocene exhibits different electrochemical characteristics depending on whether or not it is attached to a nucleotide, whether or not nucleotide is incorporated into oligonucleotide or not, and the length of any such oligonucleotide." (page 5, lines 12-15).

The artisans explicitly contemplate the use of voltammetry for the detection of the markers (page 7), wherein the artisans state that such a detection step may be carried out using one or more electrodes covered by a membrane which is able to selectively exclude molecules based on one or more characteristics, such as, "characteristics selected from size, charge and hydrophobicity," that may "assist in eliminating background current arising from, for example, charged nucleic acids or undigested labeled oligonucleotide" (page 7, lines 15-19), wherein the label used for detection a ferrocene (page, lines 25-30).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Birmingham et al., Mainelis et al., with the teachings of Braven et al., thereby arriving at the claimed invention for the following reasons.

Birmingham et al., while not explicit in stating that a electrochemical detection of PCR be conducted for the DNA/RNA analysis followed by the spore lysis and extraction of DNA/RNA therefrom, the artisans clearly imply any type of DNA/RNA analyses available in the art could be employed:

> "Once the surface membranes of the bacterial cells and/or spores have been ruptured by lysing apparatus...,the exposed nuclear material comprising specimen…is carried by conveyer...to a spore or cell RNA/DNA identifier...This identifier processes the nuclear

> material to identify the specific type of bacterial cells and/or spores comprising the specimen. The device preferably used for identifying the type of bacteria in the specimen is a time of flight mass spectrometer. However, a number of other types of bacterial spore and cell identifiers might alternatively be used..." (column 5, lines 1-10, Birmingham et al.)

Braven et al. disclose that their invention of electrochemical detection of PCR products have the advantage of sensitivity and simplicity, as well as other benefits:

> "Amplification-based DNA detection methods normally utilize a range of fluorescence chemistries or radioactive labels. Frequently, target DNA to be analysed is amplified enzymatically e.g., by PCR, then visualized using a fluorescent DNA binding dye to stain DNA size-separated by gel electrophoresis." (page 2, lines 1-4, Braven et al.)

> "The application of electrochemistry to DNA detection offers potential advantages over other detection systems in terms of sensitivity and simplicity. Their portability, robustness, ease of miniaturization and potential for high volume manufacturing makes apparatus for electrochemical methods especially suitable for clinical, food and environmental diagnostics." (page 2, lines 18-21, Braven et al.)

Given the explicit statement that the method of Braven et al., allows for a sensitive and portable detection of target nucleic acids from samples, especially in environmental diagnostic, one of ordinary skill in the art at the time the invention was made would have been motivated to combine the teachings of Braven et al. with the teachings of Birmingham et al. and Mainelis et al., who were concerned with producing portable devices for a sensitive detection of biological agents in air samples for military purposes:

> "One of the more important applications of technology requiring the lysing of bacterial cells and/or spores is in facilitating identification of biological agents that are used during bacteriological warfare or in attacks by terrorists. In order to permit known harmful bacteria to be identified, it is important that DNA and RNA comprising the bacterial cells or spores found in the suspect environment be made available for analysis. By providing a reliable and portable apparatus for lysing bacteria cells or spores collected from the environment, it will be possible to identify bacteriological warfare agents in the field so that appropriate counteractive and protective measures can be implemented. A portable field monitoring device that includes the capability to collect, concentrate, lyse, and identify bacteriological warfare agents will greatly enhance the ability of civilian populations and troops to survive such attacks." (column 2, lines 24-39, Birmingham et al.)

One of ordinary skill in the art at the time the invention was made would have been clearly attracted and thus motivated to combine the teachings of Braven et al. which allows for portable devices of sensitive detection, with the method and device taught by Birmingham et al. and Mainelis et al., which would have regarded portability and sensitivity of detection their high priority in successfully detecting bacteriological warfare agents in combat fields.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 10/590,530. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a method and device/apparatus which is drawn to the detection of biological particle (i.e,. spores) by binding biological particles from spores and extraction of

biological material (i.e., nucleic acids) by application of electrical field, followed by the analysis of the biological material from the bacterial spores.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/590,768. Although the conflicting claims are not identical, they are not patentably distinct from each other for the same reasons discussed immediately above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official

Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Young J. Kim/
Primary Examiner
Art Unit 1637
9/19/2008

/YJK/